**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| Attorney Docket No.: | **PENN-0065** |
| Inventors: | **Wolfe and Fraser** |
| Serial No.: | **08/393,066** |
| Filing Date: | **February 23, 1995** |
| Examiner: | **Deborah Crouch** |
| Customer No.: | **26259** |
| Group Art Unit: | **1632** |
| Confirmation No.: | **1030** |
| Title: | **Method of Delivering Genes to the Central Nervous System of a Mammal** |

**Electronically Submitted via EFS-Web**
Date: **September 14, 2006**

I hereby certify that this paper is being electronically submitted on the date indicated above to the Commissioner for Patents, U.S. Patent & Trademark Office (AF).

By _____
Typed Name: **Jane Massey Licata, Reg. No. 32,257**

Commissioner for Patents
U.S. Patent & Trademark Office
(AF)

# REPLY BRIEF

This reply brief is in response to the Examiner's Answer dated August 18, 2006 to address certain issues raised in the Examiner's Answer.

The Examiner alleges that the enablement rejection subject to this Appeal is based upon lack of an enabled use. It is suggested that the disclosure reveals that Appellant at the time of filing only disclosed the claimed method of stable expression for methods of treatment. The Examiner concludes that while the claims are to methods of stable expression, the use of the claims is for methods of treatment and the specification provides no guidance toward a use absent a therapeutic one. Appellants respectfully disagree.

"[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971) (emphasis in original).

While the instant claims are drawn to methods for stably expressing a selected DNA sequence in the central nervous system of a mammal, the Examiner's rejection appears to require precise predictability of treating CNS disorders. That is not, however, a requirement under 35 U.S.C. § 112, first paragraph. "Usefulness in

patent law, and in particular the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans." In re Brana, 51 F.3d, 1560, 1568 34 USPQ2d 1436, 1442-43 (Fed. Cir. 1995) (citations omitted). Therefore, having exemplified a method of stably expressing a selected DNA sequence in the central nervous system of a mammal for at least four months (see page 9 of the Appeal Brief) and further disclosed the use of such a method for treating CNS disorders, the enablement requirement has been met.

The Examiner's Answer further alleges that Appellant arguments are directed to a rejection under 35 U.S.C. §101 as lacking a credible utility and the rejection of record is not under this statute but under 35 U.S.C. §112, first paragraph as how to use. The Examiner suggests that Appellants arguments are therefore moot. See page 11 of Examiner's Answer. Appellants respectfully disagree.

In so far as the how to use prong of section 112 incorporates as a matter of law the requirement of 35 U.S.C. §101 that the specification disclose as a matter of fact a practical utility for the invention, Appellants arguments regarding utility are relevant. *In re Ziegler*, 992 F.2d 1197, 1200-01, 26 USPQ2d 1600, 1603 (Fed. Cir. 1993). Particularly considering that the entirety of the Examiner's rejection appears to question whether gene therapy is a credible utility.

It is well settled that a statement of utility and enablement in a specification must be accepted by the examiner absent reasons why one skilled in the art would have had reason to doubt the objective truth of such statement. *In re Langer*, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA 1974); *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). Given that neurotropic viral vectors, in particular HSV vectors, at the time of filing of the present invention were recognized to be useful for the purpose of gene delivery in the treatment of disease (see, *e.g.*, the teachings of Fink et al. (1996) and Eck et al. (1996) of record), it is within the skill of the art to use the vectors in the claimed method for disease treatment, and therefore the requirement of section 112, first paragraph, has been met by Appellants disclosure that the claimed method of using neurotropic viral vector is useful for that purpose. *See, e.g., In re Hitchings*, 342 F.2d 80, 89-91, 144 USPQ 637, 644-46 (CCPA 1965). To violate these requirements, the claimed method must be "totally incapable of achieving useful results." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 USPQ2d 1401, 1412 (Fed. Cir. 1992); *See also E.I. du Pont De Nemours and Co. v. Berkley and Co.*, 620 F.2d 1247, 1260 n.17, 205 USPQ 1, 10 n.17 (8th Cir. 1980)("A small degree of utility is sufficient...The claimed invention must only be capable of performing *some* beneficial function...). In this regard, stable expression of a selected DNA sequence for at least four months by an infected central nervous system cell is indeed a useful result.

Therefore, because the instant disclosure describes how to make the invention and further provides at least one credible utility for the invention, a person of ordinary skill in the art would accept without question that the instant invention is enabled.

Respectfully submitted,

Jane Massey Licata
Registration No. 32,257

**DATE: September 14, 2006**

LICATA & TYRRELL P.C.
66 E. Main Street
Marlton, NJ 08053

856-810-1515